

**REMARKS**

Claims 1-34 were pending in the application. Claim 1 has been amended. Upon entry of these amendments, Claims 1-34 will be pending and under active consideration. Claim 1 is independent.

Applicants wish to take this opportunity to thank Examiner Patterson for the courteous telephonic interview extended to the Applicants' representative, Serge Sira.

Claim 1 is amended herein to recite yield point. The amendment is supported fully by the claims and/or specification as originally filed and, thus, do not represent new subject matter. In particular, support for the amendment to Claim 1 may be found in the specification as filed at page 15, lines 23-26.

Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present invention. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action are respectfully requested.

**I. The Rejection Under 35 U.S.C. § 102(b) Should Be Withdrawn**

The Office Action, at pages 3-4, paragraph 7, rejects Claims 1-7, 14, and 20-33 as allegedly being anticipated by U.S. Patent No. 5,783,269 to Heilmann (hereinafter, "Heilmann") under 35 U.S.C. § 102(b). The Office Action alleges that Heilmann anticipates the above-mentioned claims of the present invention based on the alleged disclosure by Heilmann of structurally identical multilayer films (*i.e.*, multilayer films having similar design characteristics in terms of the arrangement, number, and composition of the layers) having identical mechanical properties. Applicants traverse respectfully.

As a threshold matter, as the Examiner is no doubt well aware, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of*

*California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Specifically, with respect to the issue of inherency, which appears to be the prime basis upon which the Examiner is basing the allegation of anticipation by Heilmann, Applicants respectfully submit that "[i]nherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Ex parte Skinner*, 2 USPQ2d 1788, 1789 (B.P.A.I. 1986). Thus, in order to establish a *prima facie* case of inherent anticipation, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (B.P.A.I. 1990).

Without acquiescing in the propriety of the arguments made in the Office Action with respect to the identity of structure of the multilayer films of Heilmann compared with those of the present invention (i.e., multilayer films having similar design characteristics in terms of the arrangement, number, and composition of the layers), Applicants assert respectfully that the mechanical properties of the films according to Heilmann are not identical with those of the films of the present invention and, in fact, the mechanical properties of films of the present invention are vastly superior to those of Heilmann.

In particular, Applicants respectfully submit that the claimed element of "no measurable yield point" is set forth neither expressly nor inherently in Heilmann. Applicants wish to clarify for the Examiner the meaning of the term "yield point" as used in the rejected claims. In the context of the present claims, "yield point" means the increase in elongation without additional stress exhibited by the films when undergoing a traction-elongation test according to DIN-ISO standards; see the specification at page 15, lines 12-26. Applicants submit respectfully that the claims of the present invention, as amended, are not inherently anticipated by Heilmann.

In particular, Applicants respectfully submit that, at best, the mechanical strength of films according to Heilmann is measured by the “drop test” method (see Heilmann, column 8, lines 20-22) whereby bags made from the film and filled with fluid are dropped from various heights to test for mechanical failure under those conditions. Applicants respectfully submit that the Examiner should not equate in any way the drop test disclosed in Heilmann with tests that measure film yield, such as those according to DIN ISO 527-1 to -3 1996. Applicants submit respectfully that the drop test, although it is a standard test of film strength and durability, is *not* a measure of film yield (*i.e.*, the amount of length the film will stretch under a given load). Thus, while Heilmann discloses films that are resistant to breakage under the drop test, Heilmann does not recite films that have no measurable yield point. In fact, Applicants submit respectfully that Heilmann teaches films that *do* have a yield point. For example, Heilmann, at column 8, lines 41-43, recites that the “film is slightly biaxially oriented during the production process at a stretching ratio of: longitudinal stretching/transverse stretching = 2.3/1.4.” Applicants submit respectfully that the claims of the present invention, as amended, are quite explicit in requiring that films of the present invention have *no measurable yield point*, whereas the films of the prior art, *e.g.*, Heilmann, do have a measurable yield point.

Applicants respectfully assert that the comparative examples specifically cited below clearly demonstrate for the record that the film compositions of the Heilmann reference do in fact have a yield point and thus do not inherently anticipate Claims 1-7, 14, and 20-33 as amended herein. The reasons supporting Applicants’ arguments are provided below.

In particular, Applicants respectfully draws the Examiner’s attention to Table 3, at pages 36 to 37 of the specification as filed, which recites a comparison of the results of traction-elongation tests (according to DIN ISO 527-1 to -3 1996) made on films manufactured according to the specifications of the prior art (labeled “Comp. Ex.”), including

that of Heilmann, with films made according to methods of the present invention (labeled "Example").

Applicants wish to take this opportunity to personally thank Examiner Patterson for the courteous telephonic interview granted to the Applicants' representative, Serge Sira. In the telephonic interview, Applicants' representative confirmed for the Examiner that, based upon confirmation with the inventors of the above-identified application, the comparative examples presented within the specification do indeed specifically include testing of film compositions falling within the scope of the specific teaching provided in the Heilmann reference, as will be explained in more detail below. Accordingly, Applicants respectfully submit for the record that although not explicitly stated in Table 3 on pages 36 to 37, the Comparative Examples 2 and 5 discussed in more detail *infra* specifically correspond to films made in accordance with the teachings of Heilmann. Applicants also respectfully submit for the record that the inventors of the above identified application specifically included in the specification as filed the comparative examples based upon the Heilmann teaching. If, however, the Examiner still deems it necessary that a Declaration Under 37 C.F.R. Section 1.132 be filed evidencing same, then Applicants will attend to filing same in due course.

Thus, specifically, while comparative Example 2, made in accordance with the teachings of Heilmann, presented in Table 3 is directed to a coextruded blow-film, comparative Example 5, made in accordance with the teachings of Heilmann, is directed to a cast film having a similar composition as comparative Example 2 in so far as the polymer materials used for the layers are concerned. The materials used for the inner layer are as follows:

- PPC2 = PP13MI0cs264 polypropylene random copolymer,
- TPE2 = Kraton G1657 = linear styrene (ethylene-butylene)-styrene-block copolym.

- TPE3 = Tuftec 14 1085L hydrogenated styrene butadiene block copolymer;

the middle layer comprises:

- PPC2 = PP13M10cs264 polypropylene random copolymer,

- TPE2 = Kraton G1657 linear styrene (ethylene-butylene)-styrene-block copolymer.

-TPE3 = Tuftec H 1085L = hydrogenated styrene butadiene block copolymer;

and the outer layer consists of:

- PPH1 = 4IE4cs278 = polypropylene homopolymer,

- TPE3 = Tuftec H 1085L = hydrogenated styrene butadiene block copolymer;

Applicants respectfully submit for the record that these aforementioned films do indeed fulfill all of the criteria of Heilmann. However, as can be seen from the Table 3, which gives the results of properties for the sterilized films of the invention and the sterilized comparative films, the blown-film of comparative example 2 (which is made in accordance with Heilmann) shows a yield in MD (machine direction) while the cast film of comparative example 5 (which is made in accordance with Heilmann) shows a yield in both, the MD and TD (measured crosswise to machine direction). All of the other comparative examples presented in Table 3 show also a yield point at least in one of the two directions MD and/or TD. Thus, Applicants submit respectfully that the films made according to the prior art, including Heilmann, indeed have a measurable yield point in this test, whereas films according to the present invention have no measurable yield point.

Moreover, Applicants respectfully submit that the only exception is comparative Example 1 (Comp. Ex. 1). However, the film of comparative Example 1, which is made in accordance with EP 0199 871 shows no yield in the sterilized state in neither of the directions, requires an outer layer made of a polyester (PET1) which is a serious drawback, as is discussed in the present application's specification at page 2, and falls outside the scope of the present claims. Applicants submit respectfully that the present invention, for the first

time, provides films consisting of 100% polyolefin materials, optionally with low amounts of rubber materials, that avoid the use of PVC and PET while retaining the advantageous mechanical properties of films of the prior art that include these materials.

Thus, Applicants respectfully submit that the comparative Examples 2 and 5 clearly demonstrate for the record that the film compositions of the Heilmann reference do in fact have a yield point. Thus, the Heilmann reference does not expressly or inherently anticipate Claims 1-7, 14, and 20-33, as amended herein.

In view of the above, Applicants requests respectfully that the rejection of Claims 1-7, 14, and 20-33 under 35 U.S.C. § 102(b) be withdrawn.

## **II. The Rejections Under 35 U.S.C. § 103(a) Should Be Withdrawn**

### **A. Rejections over Heilmann**

The Office Action, at pages 4-6, paragraphs 6-7, rejects Claims 8-9, 18-19, and 20-22 as allegedly being obvious over Heilmann, under 35 U.S.C. § 103(a). The Office Action alleges that one of ordinary skill in the art would be able to readily determine appropriate ranges of thickness, melting points, and VICAT temperatures to reach a desired end use through routine optimization. Applicants traverse respectfully.

As a threshold issue, Applicants submit respectfully that since, as noted above, Heilmann fails to teach or suggest a multilayer film having no measurable yield point as claimed in amended Claim 1, upon which rejected Claims 8-9, and 20-22 depend, it is legally impermissible for the Examiner to consider the obviousness of obtaining appropriate ranges of thickness, melting points, and VICAT temperatures to reach a desired end use through routine optimization. Indeed, the desired end use in the context of the presently claimed invention is precisely the provision of a multi-layer film of the stated composition, wherein following hot steam sterilization at 121°C or higher temperatures using a hot water spraying

process, the multi-layer film displays no measurable yield point according to DIN EN ISO 527-1 to -3 1996. Since Heilmann has been shown above by way of the comparative examples specifically cited in Table 3 to not expressly or inherently teach or even suggest a multi-layer film that displays no measurable yield point according to DIN EN ISO 527-1 to -3 1996, Applicants respectfully submit that a *prima facie* case of obviousness has not been met with respect to the invention as presently claimed.

Moreover, and by way of further clarification, Applicants respectfully submit that Heilmann teaches away from determination of appropriate ranges by routine optimization. For example, at column 6, lines 33-45, Heilmann discusses the complexities of manufacturing complex multilayer films. In particular, Applicants respectfully draw the Examiner's attention to lines 34-37, in which Heilmann recites, "it was not predictable on the basis of past experience that such a complex multi-layer film of the type according to the invention could straightforwardly be achieved with success. Heilmann recites that success in this field is "surprising" and that "practical experience has repeatedly shown that, even with the assistance of sometimes tabulated polymer properties, such as composite adhesion data, the use of such materials does not lead to success." Finally, at column 6, lines 42-45, Heilmann recites that, "in other words, solving a particular problem in a multi-layer co-extruded film by simply making a selection from known materials is not in principle straightforwardly possible."

Applicants submit respectfully that it is well known in patent law that no finding of obviousness may be made over a reference that teaches away from construction of the present invention. In an obviousness inquiry, the relevant question is whether the prior art suggests the invention and whether the prior art provides one of ordinary skill in the art with a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in

the prior art and not in the Applicants's disclosure. *In re Vacek*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added). Indeed, Applicants respectfully submit that the comparative examples presented in Table 3 of the specification as filed clearly demonstrate that it is not necessarily obvious that such a multi-layer film made according to the teachings of Heilmann would produce a film that displayed no yield point according to DIN EN ISO 527-1 to -3 1996. Applicants submit respectfully that the claimed invention is not obvious over Heilmann, because Heilmann does not teach, suggest or provide the requisite expectation of success for determination of appropriate ranges of thickness, melting points, and VICAT temperatures to reach a desired end use through routine optimization, let alone a multi-layer film that displayed no yield point according to DIN EN ISO 527-1 to -3 1996, as presently claimed. In fact, as noted above, Applicants submit respectfully that Heilmann actually teaches away from such routine optimization.

In view of the above, Applicants respectfully submit that a *prima facie* case of obviousness has not been met with respect to the invention as presently claimed. Accordingly, Applicants request respectfully that the rejections of Claims 8-9, 18-19, and 20-22 under 35 U.S.C. § 103(a) be withdrawn.

**B. Rejections Over Heilmann In Light Of U.S. Patent No. 5,686,527 To Laurin *et al.* And U.S. Patent No. 6,348,568 To Barney *et al.***

The Office Action, at page 7, paragraph 12, rejects Claims 10-13, and 15-17 as allegedly being obvious over Heilmann in light of U.S. Patent No. 5,686,527 to Laurin *et al.* (hereinafter, "Laurin"), under 35 U.S.C. § 103(a). The Office Action alleges that Laurin cures a deficiency in Heilmann wherein Heilmann does not disclose films having a modulus of elasticity of less than 100 MPa for an inner layer and at least 400 MPa for an outer layer, as recited in the present claims. While admitting that Laurin does not disclose



films having the recited moduli of elasticity (*i.e.*, Laurin discloses films having a modulus of elasticity in the range of 150-300 MPa), the Office Action alleges further that it would be obvious to one skilled in the art to vary the modulus of elasticity through routine optimization to obtain a desired result. At page 8, paragraph 13, the Office Action rejects Claim 34 of the present invention under 35 U.S.C. § 103(a) as allegedly being obvious over Heilmann in light of U.S. Patent No. 6,348,568 to Barney *et al.* (hereinafter, "Barney"). The Office Action alleges that Barney cures a deficiency in Heilmann whereby Heilmann fails to disclose packaging which stores fluid lipophilic emulsions. Applicants traverse respectfully.

As a threshold issue, since, as noted above, Heilmann fails to teach or suggest a multilayer film having no measurable yield point according to DIN EN ISO 527-1 to -3 1996, as claimed in amended Claim 1, upon which rejected Claims 10-13, 15-34 and 34 depend, and, since the Office Action does not assert that Laurin or Barney cures this fundamental deficiency, Applicants submit respectfully that it is legally impermissible for the Examiner to consider the obviousness of varying the modulus of elasticity through routine optimization to obtain a desired result or to consider packaging which stores fluid lipophilic emulsions.

Further, Applicants submit respectfully that Heilmann, either alone or in combination with Laurin or Barney, fails to show the necessary teaching, suggestion, or motivation, required to prove a *prima facie* case of obviousness. In fact, Applicants respectfully submit that the Examiner is using impermissible hindsight in an attempt to render the invention as presently claimed. Applicant wishes to remind the Examiner that "[I]t is impermissible to reconstruct the claimed invention from selected pieces of prior art absent some suggestion, teaching, or motivation in the prior art to do so." *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051-2, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988). Absent some teaching, suggestion, or motivation found within Heilmann, Laurin, or Barney that the modulus of

elasticity and/or storage of lipophilic solutions claimed by Applicants are desirable, it cannot be inferred that Applicants's invention would have been obvious to one of ordinary skill in the art. "It is insufficient to select from the prior art the separate components of the inventor's combination, using the blueprint supplied by the inventor." *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ2d 543, 551 (Fed. Cir. 1985).

Applicants submit respectfully that Heilmann does not teach, suggest, or motivate one skilled in the art to combine the teachings of Laurin or Barney with Heilmann in order to reach the present invention as claimed. Moreover, in the case of Laurin, Applicants submit respectfully that Heilmann actually teaches away from the likelihood of achieving success through routine optimization. In light of these facts and the case law noted above, Applicants submit respectfully that the Office Action has failed to meet the burden necessary for combining Laurin and Barney with Heilmann to reach the present invention as claimed. Even further, if Laurin and Barney are combined with Heilmann, Applicants submit respectfully that the Final Office Action still fails in its burden of obviousness for lack of teaching or suggestion of films having no measurable yield according to DIN EN ISO 527-1 to -3 1996. Accordingly, Applicants requests respectfully that the rejections to Claims 10-13, 15-17, and 34 under 35 U.S.C. § 103(a) be withdrawn.

### **III. Rejections Under 35 U.S.C. § 112, Second Paragraph**

At page 2, paragraph 2, of the Office Action, Claims 1-34 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out particularly and claim distinctly the subject matter regarded as the invention. In particular, in paragraph 2, the Office Action alleges that the phrase "wherein following hot steam sterilization at 121 degrees Celsius the film displays no measurable yield according to DIN EN ISO 527-1-3 1996" renders Claim 1 indefinite as the standard is not defined in the claim,

and thus the term “yield” has allegedly not been defined. The Office Action further alleges that for purposes of examination, the claimed film will be assumed to have any yield following any test. Applicants traverse respectfully.

At the outset, Applicants wish to clarify for the Examiner that in the amendment filed November 5, 2002, Claim 1 was amended, *inter alia*, to recite “yield according to DIN EN ISO 527-1 to -3. (emphasis added). Accordingly, Applicants will respond to the indefiniteness rejection assuming that this amendment has been entered.

Without acquiescing in the propriety of the rejection, and solely to advance the prosecution of the present application, Applicants amend Claim 1 herein to recite “yield point” so that the usage of the claim term “yield point” comports with the usage of the term as defined in the DIN ISO EN ISO 527-1 1996 standard.

Applicants take this opportunity to verify for the record the intended meaning of the term “yield point ” as used in the claims, so that the claims which ultimately issue will be correctly construed in accordance with the Supreme Court Decision in Markman v. Westview Instruments, Inc., 52 F.3d 367, 34 USPQ2d 1321 (Fed. Cir. 1995) (in banc), *aff’d*, 116 S.Ct. 1384, 38 USPQ2d 1461 (1996) (claims are construed in view of the patent specification and statements made of record during the prosecution history). The present specification clearly describes what is meant by the term “yield point”:

As used herein, [I]n connection with the invention, “yield” or “yield point” denotes a specific yield stress according to para. 4.3.1 (Definitions) from EN ISO 527-1 1996.”  
Specification at page 15, lines 24-26.

Moreover, Applicants respectfully submit that the Amendment to Claim 1 to now recite “yield point”, in conjunction with the prior amendment to add the particular year (1996) of the standard in question, more than adequately defines the term yield point to the skilled artisan. Therefore, Applicants respectfully submit that the metes and bounds of the

term "yield point" are thus clear and sufficiently definite to comply with the requirements of 35 U.S.C. § 112, second paragraph.

In light of the above, Applicants again respectfully wish to remind the Examiner that, while international standards such as DIN ISO standards may change over time, one skilled in the art would easily be able to determine the standard in use in the year 1996, which does not change. For the foregoing reasons, Applicants respectfully submit that Claims 1-34 particularly point out and distinctly claim that which Applicants regard as their invention. Accordingly, Applicants respectfully request that the rejection of Claims 1-34 under 35 U.S.C. § 112, second paragraph be withdrawn.

**CONCLUSION**

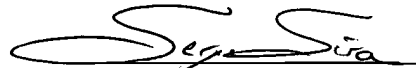
Applicants submit that the application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

**AUTHORIZATION**

Applicants believe there is no additional fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gilberto M. Villacorta", written over a horizontal line.

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